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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,243	02/06/2004	John G. Carman	81938-4299	8954

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EXAMINER	
ROBINSON, KEITH O NEAL	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/772,243	CARMAN, JOHN G.	
	Examiner	Art Unit	
	Keith O. Robinson, Ph.D.	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *21-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 29-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/6/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-20 and 29-38, in the reply filed on April 11, 2005 is acknowledged. Claims 21-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 11, 2005.

Claims 1-20 and 29-38 are under examination.

Priority

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 1-20 and 29-38 of this application. There is no support in U.S. Provisional Application No. 60/037,211, filed February 5, 1997, for producing apomictic plants by doubling the chromosome number. There is support in U.S. Application No 09/018,875, filed February 5, 1998 for producing an apomictic plant by doubling the chromosome number; therefore for the purpose of applying the prior art the priority date for the pending application is February 5, 1998.

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: PCT/US00/29905 is improperly placed under 'Earliest Foreign Applications' and should be replaced under 'Non-Provisional Applications'.

Specification Objections

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see page 2, line 33). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

5. The disclosure is objected to because of the following informalities: (a) page 1, line 5 has the phrase "claims priority to" which should be deleted and replaced with - - is the National Stage of - - ; (b) page 1, line 6 has the phrase "priority to" which should be deleted and replaced with - - benefit of - - ; and (c) page 1, line 9 has the phrase "priority to" which should be replaced with - - benefit of - - .

Appropriate correction is required.

Claim Rejections - 35 USC § 112, first paragraph – Written Description

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-20 and 29-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-10 and 13-18 are broadly drawn to a method of producing any angiospermous apomictic plant that exhibits an increased genetic stability for apomixis comprising the production of any facultatively apomictic parent plant by selection and hybridization of any sexual angiospermous plants having divergent reproductive schedules of ovule development and doubling the chromosome number of said apomictic parent (claims 1-10) or genetically modifying the parent plant so that female meiosis is aborted (claims 13-18).

The specification does not provide a written description of the broad genus of facultatively apomictic parent plants, as is broadly claimed, in terms of their genetic, morphological, and/or physiological characteristics nor is there any written description of any sexual angiospermous plants having divergent reproductive schedules of ovule development in terms of their genetic, morphological, and/or physiological characteristics.

The specification does not provide a written description of the broad genus of promoter/gene constructs that inhibit female meiosis as is broadly claimed (claim 17).

The specification fails to provide any description of the promoter/gene constructs in terms of their genetic characteristics and function.

The specification only describes the diploid apomicts existing in nature such as *Potentilla, Hierochloe, Sorbus,* and *Arabis* (see page 17, lines 3-14) and other plants such as *Antennaria, Tripsacum,* and *Sorghum* (see page 26, lines 23-25; page 27, lines 7-27; and page 28, lines10-32); however, as each species in the aforementioned genera are unique in their genetic, morphological, and physiological composition, these genera are also inadequately described.

Claims 11-12, 19-20 and 37-38 broadly drawn to any apomictic plant exhibiting increased apomixis stability.

The specification does not provide a written description of any apomictic plant exhibiting increased apomixis stability in terms of its genetic, morphological, and/or physiological characteristics.

Claims 29-36 are broadly drawn to a method of producing a genetically stabilized angiospermous apomictic plant comprising selecting any two sexual angiospermous plants having divergent reproductive schedules of ovule development, doubling the chromosome number of at least one of the sexual plants, and hybridizing said plants.

The specification does not provide a written description of any sexual angiospermous plants having divergent reproductive schedules in terms of their genetic, morphological, and/or physiological characteristics.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a

precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials". University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not description of that material". Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus". Id.

See MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

> [T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Given the failure of the specification to describe the claimed plant, methods of using it are also inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention. See the written description guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 4, 2001/ Notices: pp. 1099-1111.

Claim Rejections - 35 USC § 112 - Enablement

8. Claims 1-20 and 29-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Claims 1-10 and 13-18 are broadly drawn to a method of producing any angiospermous apomictic plant that exhibits an increased genetic stability for apomixis comprising the production of any facultatively apomictic parent plant by selection and hybridization of any sexual angiospermous plants having divergent reproductive schedules of ovule development and doubling the chromosome number of said apomictic parent (claims 1-10) or genetically modifying the parent plant so that female meiosis is aborted (claims 13-18).

The specification does not provide any guidance regarding the broad genus of facultatively apomictic parent plants, as is broadly claimed, in terms of their genetic,

morphological, and/or physiological characteristics nor is there any guidance regarding any sexual angiospermous plants having divergent reproductive schedules of ovule development in terms of their genetic, morphological, and/or physiological characteristics. Also, the specification does not provide any evidence the broad genus of angiospermous plants can all be successfully crossed nor is there any evidence of chromosome doubling of the broad genus of apomictic plants.

The specification only teaches the diploid apomicts existing in nature such as *Potentilla, Hierochloe, Sorbus,* and *Arabis* (see page 17, lines 3-14) and other plants such as *Antennaria, Tripsacum,* and *Sorghum* (see page 26, lines 23-25; page 27, lines 7-27; and page 28, lines10-32); however, as each species in the aforementioned genera are unique in their genetic, morphological, and physiological composition, and the specification fails to teach every species nor does the specification teach that intergeneric, interspecific, as well intraspecific hybridization would be successful. In fact, the specification teaches that "Most apomicts are outcrossing perennials" and "inbreeding apomicts and annual apomicts are extremely rare" (see page 14, lines 11-12). Thus, the selection and hybridization of any sexual angiospermous plants having divergent reproductive schedules of ovule development of inbred and annual plants would require undue trial and error experimentation because one skilled in the art would have to screen all possible sexual angiospermous plants to determine each and every one of these plants reproductive schedules as well as make numerous crosses to see which, if any, would hybridize. In addition, the specification teaches that the families of

the Asteraceas, Poaceae, and Rosaceae "contain 75% of all apomictic genera" (see page 14, lines 18-21).

The specification only teaches the use of *Tripsacum* species *laxum, pilosum, zopilotense,* and *bravum* to produce apomictic plants wherein *laxum* and *pilosum* are crossed and the resulting F1 is then crossed with *zopilotense* or *bravum* to produce "stable apomicts with about 80% diplosporous embryo sac formation and 20% abortive meiocyte or sexual embryo sac formation" (see page 28, line 30 to page 29, line 2) nor is there any evidence that Applicant has produced an apomictic plant from any of these genera.

Claims 11-12, 19-20 and 37-38 broadly drawn to any apomictic plant exhibiting increased apomixis stability.

The specification does not provide any guidance regarding any apomictic plant exhibiting increased apomixis stability in terms of its genetic, morphological, and/or physiological characteristics nor is there any evidence of an apomictic plant exhibiting increased apomixis stability. The specification does teach "Because most apomicts are allopolyploids... allopolyploidy is probably the most common form of apomixis stabilization (see page 14, lines 26-27); however, there is no evidence in the specification of any allopolyploid, segmental allopolyploid, nor autopolyploid apomictic plant as is claimed in claims 12, 20 and 38.

Claims 29-36 are broadly drawn to a method of producing a genetically stabilized angiospermous apomictic plant comprising selecting any two sexual angiospermous

plants having divergent reproductive schedules of ovule development, doubling the chromosome number of at least one of the sexual plants, and hybridizing said plants.

The specification does not provide any guidance regarding any sexual angiospermous plants having divergent reproductive schedules in terms of their genetic, morphological, and/or physiological characteristics nor is there any evidence of any angiospermous apomictic plant produced by the chromosome doubling of at least one of the sexual plants or the hybridization of any plants.

Finally, the specification does not provide any guidance for distinguishing a facultatively apomictic plant from any other plant.

Bashaw (Apomixis and its application in crop improvement, *In* Hybridization of crop plants, Fehr et al (eds.), pp. 45-63, 1980) teaches that it is difficult to detect facultative apomixis, as there will be some variant plants among its progeny (see page 53, second paragraph).

The production of apomictic plants is unpredictable due to environmental and genetic reasons.

The specification teaches that "in most apomicts, a certain percentage of seeds produced by a single apomictic plant will form sexually, and this...is often influenced by environmental factors" (see page 2, lines 6-8) and that "the parental sexual phenotypes of apomicts are polygenic coadaptations, ...encoded by unique groupings of alleles that function cooperatively to confer fitness to specific ecotypes adapted to specific environments" (see page 13, lines 18-23). Koltunow et al (Annu. Rev. Plant Biol. 54:

547-574, 2003) teach that expressivity of apomixis may be affected by genetic modifiers or environmental conditions (see page 555, second paragraph).

Bashaw (Apomixis and its application in crop improvement, *In* Hybridization of crop plants, Fehr et al (eds.), pp. 45-63, 1980) teaches that environmental factors may affect the stability of the reproductive process in facultative apomicts (see page 61, section VII).

Savidan (Plant Breeding Reviews 18: 13-86, 2000) teaches that apomixis is a complex trait wherein the final phenotype is influenced by multiple, yet unknown, regulatory factors (see page 34, first paragraph). Bashaw teaches that the breeding of facultative apomicts poses a special problem because of unpredictable progeny variation (see page 46, second paragraph).

Asker (Hereditas 91: 231-240, 1979) teaches that most apomicts combine apomictic and sexual reproduction wherein during later years, traces of sexuality have been shown to occur even in taxa within genra that have been considered obligatorily apomictic (see page 233, first column, second paragraph).

van Dijk et al (Trends in Plant Science 5(2): 81-84, 2000) teach that apomixis in angiosperms "occurs in ~10% of angiosperm families but only ~0.1% of species" (see page 82, second column, second paragraph) and that apomixis can cause reduced levels of genetic variation due to deleterious mutations and lack of adaptive potential to changing environments (see page 82, third column, third paragraph). van Dijk et al also teach that (1) ploidy hybridization barriers may restrict the introgression of natural apomixis genes, (2) that in some species apomixis can only be transmitted through

diploid pollen, and (3) that a number of natural apomicts are triploid and the vast majority of pollen grains are chromosomically unbalanced (see page 83, first column, paragraphs 4-6). Finally, van Dijk et al teach that "Virtually nothing is known about the transmission of natural apomixis genes in the field or how apomixis genes affect fertility in inter-specific hybrids" (see page 84, first column, second paragraph).

Grimanelli et al (Trends in Genetics 17(10): 597-604, 2001) teach that the genetic control of apomixis is unclear and that apomixis is found in highly heterozygous and genetically poorly characterized species, making its genetic dissection difficult (see page 599, second column, first paragraph).

Bashaw teaches that in breeding of apomicts, hybrids may be difficult to identify because the plants tend to be highly heterozygous (see page 57, second paragraph).

de Wet et al (Caryologia 23: 183-187, 1970) teach that breeding for apomixis by sexual hybridization with a group of species or related groups of species is unpredictable because the resulting plants may be genetically unstable (see page 183, Abstract; page 184, Table 1; and page 184, line 1 to page 186, line 17) and that it is unpredictable to select apomictic plants on the basis of distinct maternal morphological types among the progeny of a cross (see page, Table 1; and page 184, line 1 to page 186, line 18).

While chromosome doubling is well within the level of one skilled in the art, the state of the art teaches that it is unpredictable.

Dewey (Crop Sci. 17:106-111, 1977) demonstrates the unpredictability in interspecific crosses and teaches that chromosome doubling can reduce vegetative

vigor (see Abstract; page 107, second column, first paragraph, and Figure 1 and Table 1; page 110, first column, third paragraph).

Barnabas et al (Theor. Appl. Genet. 81:675-678, 1991) teach that it is not clear whether spontaneously doubled genomes differ from chemically doubled genomes in the degree of genetic stability (see page 677, second column, second paragraph).

Neither the instant specification nor the prior art provides evidence that such unpredictability in chromosome doubling is not common, such that the claimed methods would not produce similar results.

Given the unpredictability of producing apomictic plants, the unpredictability of stabilizing apomixis in plants, the unpredictability of crosses between sexual lines and apomictic lines, the breadth of the claims, the lack of guidance regarding the broad genus of facultatively apomictic parent plants, the absence of working examples of the invention regarding the broad genus of facultatively apomictic parent plants, and the unpredictability of chromosome doubling as shown in the prior art, it would require undue experimentation for one skilled in the art to make and use the invention as it is broadly claimed.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 11-12, 19-20 and 37-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Lutts et al (Euphytica 78: 19-25, 1994). The claims are broadly drawn to any apomictic plant wherein said plant may be an allopolyploid, segmental allopolyploid, or autopolyploid.

Lutts et al disclose apomictic plants of the genus *Brachiaria* (see page 20, Materials and Methods and Table 1; and page 23, Table 2). See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products. See *In re Best*, 195 USPQ 430, 433 (CCPA 1997), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

Claim Rejections - 35 USC § 102/103

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 1-10, 13-18 and 29-36 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lutts et al (Euphytica 78: 19-25, 1994). The claims are broadly drawn to a method of producing any angiospermous apomictic plant with increased genetic stability for apomixis comprising producing any facultatively apomictic parent plant by selecting and hybridizing any sexual angiospermous plants having divergent reproductive schedules of ovule development and doubling the chromosome number of the apomictic parent plant.

Lutts et al disclose a method of producing an angiospermous apomictic plant with increased genetic stability for apomixis by hybridizing sexual angiospermous plants and doubling the chromosome number of the apomictic parent (see page 20, Materials and Methods and Table 1).

Lutts et al do not teach hybridization with a plant containing a meiotic mutant or a plant of a different ploidy level. Lutts et al also do not teach genetically modifying the parent plant by B_{III} hybridization or by transforming the parent with a promoter/gene construct.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the teachings of Lutts et al to use the method of producing an angiospermous apomictic plant that exhibits increased genetic stability for apomixis.

One of ordinary skill in the art would have been motivated to modify the teachings of Lutts et al to produce a method of producing an angiospermous apomictic plant that exhibits increased genetic stability for apomixis because the use of the method would produce superior plants morphologically close to the female progenitor and express both hybrid vigor and apomictic reproduction, as suggested by Lutts et al (see page 19, first column, second paragraph). In addition, one of ordinary skill in the art would have a reasonable expectation of success based on the success of Lutts et al in using colchicine to double the chromosome number and hybridizing apomictic plants to produce apomictic plants.

Conclusion

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is 571-272-2918. The examiner can normally be reached on Monday - Friday 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, Ph.D. can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Keith O. Robinson, Ph.D.

June 6, 2005

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER